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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of

Meeting; Request for Comments

SUMMARY: This notice announces a meeting of the Scientific Advisory Committee on

Alternative Toxicological Methods (SACATM). SACATM advises the Interagency

Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the

National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative

Toxicological Methods (NICEATM), and the Director of the National Institute of

Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties

of ICCVAM and activities of NICEATM. The meeting is open to the public.

Registration is requested for both public attendance and oral comment and required to

access the webcast. Information about the meeting and registration is available at

http://ntp.niehs.nih.gov/go/32822.

DATES:

Meeting: September 16, 2014, beginning at 8:30 AM Eastern Daylight Time and

continuing until adjournment at approximately 5:00 PM.

Written Public Comments Submissions: Deadline is September 2, 2014.

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Registration for Meeting and Oral Comments: Requested by September 9, 2014.

Registration to View Webcast: Deadline is September 16, 2014. Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709

Meeting Webpage: The preliminary agenda, registration, and other meeting materials are at http://ntp.niehs.nih.gov/go/32822.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 919-541-9834, fax: (301) 480-3272, email: whiteld@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2136, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda and Other Meeting Information: A preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information, when available, will be posted on the SACATM meeting website

(http://ntp.niehs.nih.gov/go/32822) or is available upon request from the Designated Federal Officer. Following the meeting, summary minutes will be prepared and available on the SACATM website or upon request.

Meeting and Registration: This meeting is open to the public with time scheduled for oral public comments. The public may attend the meeting at NIEHS, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to attend and/or provide comments are encouraged to register at http://ntp.niehs.nih.gov/go/32822 by September 9, 2014, to facilitate planning for the meeting. Individuals interested in the meeting are encouraged to access this website to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in person is available at niehs.nih.gov/about/visiting/index.cfm. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541-4363 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Both written and oral public input on the agenda topics is invited. Written comments received in response to this notice will be posted on the meeting website and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written

comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document. Time is allotted during the meeting for presentation of oral comments and each organization (sponsoring organization or affiliation) is allowed one time slot per topic. At least 7 minutes will be allotted for each speaker, and if time permits, may be extended up to 10 minutes at the discretion of the chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than for registered speakers and will be determined by the number of persons who register at the meeting. In addition to in-person oral comments at the meeting, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The lines will be open from 8:30 AM until approximately 5:00 PM, although public comments will be received only during the formal public comment periods, which will be indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting.

Persons wishing to present oral comments are encouraged to register using the SACATM meeting registration form (http://ntp.niehs.nih.gov/go/32822), indicate the topic(s) on which they plan to comment, and, if possible, send a copy of their statement to whiteld@niehs.nih.gov by September 9, to enable review by SACATM, NICEATM, ICCVAM, and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 30 copies of the statement for distribution and to supplement the record.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found at http://ntp.niehs.nih.gov/go/iccvam and http://ntp.niehs.nih.gov/go/niceatm.

SACATM was established in response to the ICCVAM Authorization Act [Section 285*l*-3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

SACATM provides advice on priorities and activities related to the development,

validation, scientific review, regulatory acceptance, implementation, and national and

international harmonization of new, revised, and alternative toxicological test methods.

Additional information about SACATM, including the charter, roster, and records of past

meetings, can be found at http://ntp.niehs.nih.gov/go/167.

Dated: July 7, 2014.

John R. Bucher,

Associate Director, National Toxicology Program.

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